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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,749

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Jean-Loup Lemesre

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

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1645

MAIL DATE

DELIVERY MODE

10/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,749	Applicant(s) LEMESRE ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment filed 6-22-09 has been entered into the record. Claims 1-5 and 7-9 have been cancelled. Claims 6 and 10-12 are pending. Claims 6 and 10 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 11 and 12 drawn to an invention nonelected in the response filed 10-8-08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants request for rejoinder is noted, however the product claims are not allowable at this time.

Rejections Withdrawn

The rejection of claim 6 over Lemesre US Patent Application No. 20030068690 is withdrawn in view of the amendment to the claims to recite "electrophoretically pure".

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite "said glycoprotein being electrophoretically pure". The term electrophoretically pure indicates that the glycoprotein has been purified to such a degree that it presents a single band on a gel stained for proteins. Applicant points in particular to pages 10, 11, 14 and Figure 5. A review of the specification pages 10, 11 and 14 finds no support for any purity limitation and no written description of analysis of purification by electrophoresis or examination of purification of a glycoprotein. As such, the text of these pages does not provide for conception by way of written description for this new limitation. Figure 5 gives the level of production of the protein by Western blotting, using an anti-PAS antibody. Western blotting is not a means to measure purity of any preparation because the antibody only detects the cognate antigen to which it was raised. By virtue of the antibody's specificity, the western blot only detects those proteins that are bound by the antibody and does not reveal the presence or absence of any other non-antibody binding proteins present in the gel. Clearly, western blotting cannot demonstrate that a protein has been purified to the extent that it is "electrophoretically pure". In fact the presence of other excreted/secreted proteins in Figure 5B clearly shows that the glycoprotein was not electrophoretically pure in view of the detection of the presence of other antibody-binding proteins in the sample that was tested. For the constitutive protein western blot, the description at page 14 indicates that "Figure 5 gives the level of production of the protein by Western blotting, using and anti-PAS antibody (Figure 5A: constitutive proteins; figure 5B: excreted/secreted proteins)". The level of protein production indicates amount and not purity. There are no coomassie blue or silver stained electrophoretic gels providing evidence of possession at the time of filing of an

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electrophoretically pure glycoprotein as claimed. Coomassie blue and silver staining are conventional protein/glycoprotein stains for electrophoretically separated components (Breitlow, S. Promega Notes Magazine Number 35, February 1992). There are no gels or experimental evidence indicating the purity of any preparation of the claimed glycoprotein. Applicants cannot rely upon a western blot to establish a protein purification standard because the method simply does not reveal or measure total protein present in the sample or loaded onto the gel and does not utilize detection methodology that would allow the skilled artisan to see the presence or absence of other proteins in the sample.

As such, the specification does not convey to one having ordinary skill in the art at the time that the invention was made that Applicants were in possession of an electrophoretically pure immunogenic glycoprotein as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the glycoprotein is encoded by a nucleic acid sequence comprising SEQ ID NO:1. However, the glycoprotein is not encoded by SEQ ID NO:1 only the protein portion thereof. The glycosylation of the protein is a post-translational event that modifies the protein encoded by the nucleic acid sequence. As such, the claim is technically incorrect because the nucleic acid of the claim is not encoded by SEQ ID NO:1. Applicants may wish to consider amendment of the claim to recite --An immunogenic

glycoprotein, the protein being encoded by the nucleic acid sequence set forth in SEQ ID NO:1....- to obviate this rejection.

Status of Claims

Claims 6 and 10 stand rejected. Claims 11 and 12 are withdrawn from consideration.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner